IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

THIERRY CHIAPELLO,	*	
Plaintiff,	*	
v.	*	**Civil Case No. SAG-23-3149**
CORIN USA LIMITED, CO. f/k/a CORIN USA LIMITED, INC., *et al.,*	*	
Defendants.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Thierry Chiapello ("Plaintiff") filed this products liability action against Defendants Corin USA Limited, Co. f/k/a Corin USA Limited, Inc. and Corin Group PLC (collectively "Corin")[1] and Stryker Corporation, Stryker Sales Corporation, and Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics ("Howmedia") (collectively "Stryker"), alleging claims suffered from implantation of a medical device, the Cormet Hip Resurfacing System ("CHRS"). ECF 1-2. Plaintiff voluntarily dismissed the claims against Stryker Corporation and Stryker Sales Corporation. ECF 24, 25. Both Corin and Howmedia filed motions to dismiss the complaint on the ground of preemption. ECF 25 (Corin) and ECF 28 (Howmedia). Plaintiff opposed the motions, ECF 29, and Corin and Howmedia filed replies, ECF 30 (Corin) and ECF 31 (Howmedia). No hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2023). For the reasons stated below, the motions to dismiss will be granted and the complaint will be dismissed without prejudice.

[1] Corin states that the correct names of the two entities are Chip 4736 and Corin Group Limited rather than Corin USA Limited, Co. and Corin Group PLC respectively. This Court's memorandum opinion and order apply equally to the two entities, regardless of the names used.

I. FACTUAL BACKGROUND

The facts described herein are derived from Plaintiff's Complaint and are taken as true for purposes of this motion. ECF 1-2. In the early 1990s, Corin developed a metal-on-metal hip implant design for use in hip replacement surgeries.[2] *Id.* ¶ 34. Corin continued to refine its device, and began applying for clearances to sell its devices in the U.S. in the late 1990s. *Id.* ¶¶ 36, 37. The CHRS is a hip resurfacing system using a cobalt-chromium metal mix to "cap" the head surface and the acetabular surface of the hip joint. *Id.* ¶¶ 4, 46. Corin submitted a Pre-Market Approval (PMA) application to the FDA for the CHRS in March 2005. *Id.* ¶ 38. Stryker served as a sponsor for that application. *Id.* The FDA conditionally approved the PMA application for the CHRS in July 2007, with conditions including but not limited to a requirement that Corin submit adverse rection and device defect reports within ten days of receiving knowledge of such events. *Id.* ¶ 39. Following PMA approval, Stryker began marketing Corin's CHRS implants throughout the United States. *Id.* ¶¶ 40, 42.

Plaintiff alleges that, at the time they submitted the CHRS for PMA approval and thereafter, Corin and Stryker knew or should have known that metal-on-metal hip resurfacing posed a risk of Adverse Reactions to Metal Debris (ARMD) and "cobaltism," resulting from elevated levels of cobalt in the bloodstream. *Id.* ¶¶ 4, 46. Plaintiff also alleges that Corin knew or should have known that revision of a hip resurfacing is more damaging than revision of a total hip replacement, and it falsely claimed that future revision surgery after resurfacing is an easier operation. *Id.* ¶¶ 50–52. Plaintiff alleges that the detrimental biological effects of metal-on-metal

[2] According to the Complaint, metal-on-metal hip implants had been largely abandoned after use in the 1960s and 1970s, because particulate metal debris spread in the patients' bodies and caused poor clinical outcomes. *Id.* ¶ 32. The industry moved to use of plastics and ceramics, which eliminated those risks but proved less durable and required more revision surgeries. *Id.* ¶ 33. A renewed interest in metal-on-metal options ensued.

hips have been well known for decades prior to the FDA's approval of the CHRS, *id.* ¶¶ 54–78, and that the scientific literature continued to demonstrate those ill effects after the device's approval, *id.* ¶¶ 79–110.

In fact, on January 17, 2013, the FDA issued a Safety Communication stating that there are unique risks associated with metal-on-metal hip implants.[3] *Id.* ¶ 111. The Safety Communication recommended that patients experiencing problems should consider metal ion testing because of the likelihood of "adverse local tissue reaction" or "adverse reaction to metal debris" from the cobalt and chromium ions released from the devices into the body. *Id.* ¶¶ 111–12. The following day, the FDA published proposed rules requiring all manufacturers of metal-on-metal hip devices to establish the safety of their devices, even those already approved on the market. *Id.* ¶ 113. The FDA issued a final order requiring manufacturers to submit new PMA applications for their marketed metal-on-metal hip systems on February 18, 2016. *Id.* ¶ 115.

Plaintiff had two CHRS hip surgeries performed by Dr. Michael Mont in 2011 and 2012. *Id.* ¶ 123. He began developing low testosterone-related symptoms in 2013, and continued to have soft tissue injuries, fatigue, migraines, and mental health issues, among other medical conditions, over the ensuing years. *Id.* ¶¶ 124, 126, 129–31, 133–34. None of his treating physicians checked his blood cobalt and chromium levels. *Id.* ¶ 132, 135. Finally, in 2020, Plaintiff sought treatment from Dr. Mont's partner, Dr. Peroutka, for a new hip injury. *Id.* ¶ 137. Dr. Peroutka recognized the possible connection between Plaintiff's symptoms and his CHRS implants and ordered testing

[3] The Complaint references a "Field Safety Notice" and recall by Stryker, but provides no detail to permit this Court to understand what transpired. *Id.* ¶¶ 108, 109. Those allegations appear potentially inconsistent with other allegations (in the form of group pleading) that the Defendants (including Stryker) continued to market the device.

that confirmed he had high cobalt-chromium levels. *Id.* ¶ 138. Plaintiff underwent two revision surgeries in late 2020, but continues to suffer the effects of the implants. *Id.* ¶ 141–42.

II. LEGAL STANDARDS

Under Rule 12(b)(6), a defendant may test the legal sufficiency of a complaint by way of a motion to dismiss. *See In re Birmingham*, 846 F.3d 88, 92 (4th Cir. 2017); *Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159, 165–66 (4th Cir. 2016); *McBurney v. Cuccinelli*, 616 F.3d 393, 408 (4th Cir. 2010), *aff'd sub nom.*, *McBurney v. Young*, 569 U.S. 221 (2013); *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). A Rule 12(b)(6) motion constitutes an assertion by a defendant that, even if the facts alleged by a plaintiff are true, the complaint fails as a matter of law "to state a claim upon which relief can be granted."

Whether a complaint states a claim for relief is assessed by reference to the pleading requirements of Fed. R. Civ. P. 8(a)(2). That rule provides that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The purpose of the rule is to provide the defendants with "fair notice" of the claims and the "grounds" for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007).

To survive a motion under Fed. R. Civ. P. 12(b)(6), a complaint must contain facts sufficient to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) (citation omitted) ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions' ..."); *see also Willner v. Dimon*, 849 F.3d 93, 112 (4th Cir. 2017). However, a plaintiff need not include "detailed factual allegations" in order to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555. Further, federal pleading rules "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 11 (2014) (per curiam).

Nevertheless, the rule demands more than bald accusations or mere speculation. *Twombly*, 550 U.S. at 555; *see Painter's Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013). If a complaint provides no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action," it is insufficient. *Twombly*, 550 U.S. at 555. Rather, to satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth "enough factual matter (taken as true) to suggest" a cognizable cause of action, "even if ... [the] actual proof of those facts is improbable and ... recovery is very remote and unlikely." *Id.* at 556.

In reviewing a Rule 12(b)(6) motion, a court "must accept as true all of the factual allegations contained in the complaint" and must "draw all reasonable inferences [from those facts] in favor of the plaintiff." *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011) (citations omitted); *see Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015); *Kendall v. Balcerzak*, 650 F.3d 515, 522 (4th Cir. 2011), *cert. denied*, 565 U.S. 943 (2011). But a court is not required to accept legal conclusions drawn from the facts. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986). "A court decides whether [the pleading] standard is met by separating the legal conclusions from the factual allegations, assuming the truth of only the factual allegations, and then determining whether those allegations allow the court to reasonably infer" that the plaintiff is entitled to the legal remedy sought. *A Soc'y Without a Name v. Virginia*, 655 F.3d 342, 346 (4th Cir. 2011), *cert. denied*, 566 U.S. 937 (2012).

III. ANALYSIS

A. Preemption

The federal Food Drug and Cosmetic Act ("FDCA") includes the Medical Device Amendments ("MDAs") that classify medical devices into three categories. The categories range from Class I devices, that present no unreasonable risk of illness or injury and are subject to

minimal regulation, to Class III devices, which either "present[] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Class III devices are only approved for marketing after they are subjected to a rigorous PMA process by the FDA. *Id.* In that process, the FDA weighs "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* § 360c(a)(2)(C). On average, the FDA spends 1,200 hours reviewing information about the safety and efficacy of each Class III device, granting PMA "only if it finds there is a reasonable assurance of the device's safety and effectiveness." *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (internal quotation marks and citations omitted). Once the FDA awards PMA for a device, the manufacturer is prohibited under federal law from making "changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness" without obtaining FDA approval. *Id.* Manufacturers have ongoing duties to report adverse incidents to the FDA and to "periodically inform the FDA about data from clinical studies or scientific literature related to the device." *Walker v. Medtronic, Inc.,* 670 F.3d 569, 574 (4th Cir. 2012) (internal citations omitted).

The FDCA's statutory scheme contains two preemption provisions relevant to this case. Congress specified that any action "for the enforcement, or to restrain violations" of the FDCA must be brought "by and in the name of the United States." 21 U.S.C. § 337(a). And the MDA provides that no state may impose "any requirement" regarding the safety or effectiveness of a medical device "different from, or in addition to, any requirement applicable ... to the device" under federal law. 21 U.S.C. § 360k(a). Together, those two statutory provisions preempt "nearly

all types of claims concerning FDA-approved medical devices." *In re Medtronic, Inc., Sprint Fidelis Leads Products Liabl. Litig.,* 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009).

The Supreme Court, however, has carved out a narrow path for some plaintiffs' state-law claims against device manufacturers to proceed. To bring viable claims against Class III medical device manufacturers, plaintiffs must assert state-law claims that are parallel to federal law. A parallel claim is one that does not impose requirements different from those imposed on the manufacturers by federal law. *Riegal*, 552 U.S. at 330. Essentially, then, to state a claim, a plaintiff meet both prongs of a two-prong test: (1) the plaintiff must allege that the manufacturer failed to comply with a specific federal requirement applicable to the device, and (2) the plaintiff must explain how that violation of the federal requirement also violated a provision of state law, since the FDCA forbids a plaintiff from advancing a private claim for violation of the FDCA. *Ellis v. Smith & Nephew, Inc.*, Civ. No. TMC-15-545, 2016 WL 7319397, at *3 (D.S.C. Feb. 16, 2016).

The Supreme Court has also made clear that plaintiffs cannot bring private claims amounting to an assertion of "fraud on the FDA." In *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001), the Supreme Court held that the "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." The conflict is that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* Similarly, the FDA retains control over monitoring and managing postapproval requirements, because 21 C.F.R. § 814.82(c) provides that "[f]ailure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA." Those requirements, too, are not properly the subject of private claims for enforcement.

B. Plaintiff's Claims

Plaintiff asserts two identical sets of five state-law claims, each set pertaining to one of his two hip surgeries (right and left). The five claims are strict product liability for design defect, strict product liability for failure to warn, negligence, negligent failure to warn, and breach of implied warranty. ECF 1-2. Although the Complaint identifies five distinct legal claims, the allegations overlap considerably. For example, Counts II (strict liability for failure to warn) and III (negligence) each allege Defendants' failure to train physicians, and Counts II, III, and IV each allege Defendants' failure to warn patients and physicians and to recall the device. Because of the substantial overlap and the two prongs that must be met to escape preemption, this Court will begin by reviewing the various federal violations Plaintiff has alleged to ascertain whether he has pled any viable parallel claims, before turning to the individual state-law legal theories he espouses.

Plaintiff's Complaint conclusorily alleges eleven different "ways" in which he believes the Defendants failed to comply with the FDCA, its implementing regulations, and their duties under the PMA orders approving the CHRS. ECF 1-2 ¶¶ 146–57. Each allegation states that the Defendants engaged in the violative conduct "either individually or jointly." *Id.* And in terms of facts supporting the alleged violations, Plaintiff lists ten actions taken "on information and belief" by "the Corin and Stryker Defendants." *Id.* ¶¶ 158–68. In other words, Plaintiff's Complaint sets forth no specific factual allegations about conduct taken by any particular Corin or Stryker defendant. *See, e.g.*, *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (quoting *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1158) ("Plaintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' in order to avoid preemption."); *Funk v. Stryker Corp.,* 631 F.3d 777, 782 (5th Cir. 2011) (affirming dismissal of complaint that failed to allege "how the manufacturing process failed, or how it deviated from the FDA approved manufacturing

process"). Plaintiff must offer a factual basis for his claims in order to proceed to discovery. *See In re Kunstler,* 914 F.2d 505, 516 (4th Cir. 1990) ("The need for discovery to complete the factual basis for alleged claims is not an excuse to allege claims with no factual basis.").

In addition, Fourth Circuit case law holds that a complaint cannot rely on "indeterminate assertions against all defendants." *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 422 (4th Cir. 2015) (internal quotation marks and citations omitted). This holds true even when some of those defendants are corporate subsidiaries or affiliates of one another. *See id*. at 423 (" 'The fact that two separate legal entities may have a corporate affiliation does not alter [the] pleading requirement' to separately identify each defendant's involvement in the conspiracy.") Here, Plaintiff has sued five separate entities and has not made precise factual assertions against any.

Notwithstanding the improper group pleading, this Court examines whether the factual allegations support a plausible claim for relief or whether they are instead preempted by federal law. The general allegations that Plaintiff has made can be separated into seven categories, which are addressed below:

1. Design Controls (paragraphs 147–49, 180, 206)[4]

In these paragraphs, Plaintiff alleges deficiencies in the design process, such as the failure to establish *in vivo* life expectancy. The design process is reviewed and approved by the FDA as part of its extensive PMA review. Plaintiff's expression of dissatisfaction with elements of the design process reflects one of two things: (1) an example of "fraud on the FDA" by the Defendants during the approval process, which would be preempted by *Buckman*, or (2) dissatisfaction with

[4] The paragraph references here are those in the first five counts of Plaintiff's complaint (relating to his right hip). For simplicity, this Court has not included the duplicative second set of paragraph references in the near-identical second five counts pertaining to Plaintiff's left hip, but those counts are subject to dismissal for the same reasons.

the FDA's level of scrutiny of the available information at the time it granted PMA. Either way, Plaintiff's claims relating to the design controls are preempted by the MDAs, because imposing more stringent design requirements than those imposed by the FDA would not be permissible.

2. "Bio-Compatibility Studies" (paragraph 150)

Plaintiff asserts that the Defendants "failed to conduct adequate bio-compatibility studies," but cites no specific federal provision requiring any such studies. Accordingly, this paragraph fails to state a parallel claim.

3. "Component Discrepancy" Allegations (paragraphs 151–52)

This Court does not understand the assertions in these paragraphs. As best this Court can tell, Plaintiff may have copied this language from similar cases involving hip replacement or resurfacing. Those courts, however, expressed similar confusion about the meaning of these assertions. *See, e.g.*, *Shuker v. Smith & Nephew PLC*, Civ. No. 13-6158, 2015 WL 1475368, at *17 (E.D. Pa. Mar. 31, 2015) ("The remaining allegations in Count II are difficult to categorize and, in many instances, incomprehensible to the Court. For example, Plaintiffs allege Defendants failed to identify, capture, and/or correct the 'component discrepancy,' in violation of 21 C.F.R. § 820.80, but do not explain what this term, which does not appear in the cited regulation, refers to."). To the extent Plaintiff intends to assert a manufacturing defect involving the particular CHRS systems implanted in his hips, he has alleged no facts to support that theory.

4. Post-Approval Reporting Requirements (paragraphs 153–55, 157, 159–62, 193–95, 222)

Plaintiff also asserts a series of failures to address complaints about the CHRS, adverse incident reports, device investigations, and reports of user error. Several of these reporting duties are owed only to FDA, and Plaintiff cannot enforce those requirements of the MDA under *Buckman. See Ellis*, 2016 WL 7319397, at *7 (reasoning that claim resting on failure to provide

reports to FDA was impliedly preempted). To the extent these requirements would establish some duty owed to Plaintiff, Plaintiff has neither identified the duty existing under state law nor alleged any facts to substantiate a violation of any such duty. *See Simmons v. Boston Sci. Corp.,* Civ. No. PA-12-7962, 2013 WL 1207421, at *5 (C.D. Cal. Mar. 25, 2013) (finding a complaint preempted where it "merely baldly asserts that Defendants failed to report adverse events," ruling that the "unsupported allegations, without more, are insufficient [to] state a claim under *Twombly*"). As set forth above, Plaintiff cannot simply cite the requirement in order to state a valid claim. Finally, with respect to the allegations in paragraph 157 relating to investigation of user error, Plaintiff fails to cite any federal requirement to conduct such investigation.

5. Failure to Recall or Stop Marketing the Device (paragraphs 156, 208, 226, 243–48)

This claim is clearly preempted, as it suggests a duty to recall or stop marketing a device that had been approved for PMA by the FDA. Any state-law based duty to stop marketing the device would be in addition to federal requirements (permitting marketing) and barred by *Riegel*. The same analysis pertains to Plaintiff's claim for breach of "implied warranty of merchantability," because the FDA determined in its PMA analysis that the device was merchantable and fit for its intended use, despite the identified risks.

6. Failure to Implement Quality Control (paragraphs 196, 220–21)

Plaintiff alleges a failure to take preventative and corrective actions that address "non-conformance" and other quality control issues, including latent manufacturing defects. But he has not identified a federal statute or regulation requiring such actions. Instead, such actions appear to be different from or in addition to the requirements of the PMA process.

7. Failure to Warn Others and Train Physicians (paragraphs 166–68, 175–76, 180, 187–92, 208, 210–12, 224–25, 227–31, 237–39)

Throughout Plaintiff's Complaint, he alleges a failure to warn patients, physicians, and the FDA about risks of the device and a failure to train physicians. With respect to training, Plaintiff has not alleged any specific deficiencies in the training or how the training failed to comply with a federal requirement. And Plaintiff has not provided any facts relating to the training received by Dr. Mont, the physician who performed Plaintiff's surgeries.

Plaintiff's failure to warn claims fare no better. As noted above, the warnings accompanying a device are established during the PMA process, and a manufacturer is not permitted to deviate from the approved warnings in its marketing of the device. *See* 21 C.F.R. § 814.80. Any claims relating to information that should have been provided to the FDA under its requirements fall, as noted above, within the FDA's purview to enforce.

At base, Plaintiff's Complaint suggests that the FDA approved and permitted Defendants' initial and continued marketing of metal-on-metal hip implants when it should not have done so, in light of medical studies and materials readily available to the public. Such allegations, while understandable given Plaintiff's unfortunate experience with his CHRS devices, do not circumvent the problem of federal preemption mandated by Congress and the Supreme Court. In his Complaint, Plaintiff has not alleged sufficient facts to support a plausible claim that any Corin or Stryker defendant violated the federal requirements that the FDA put in place for the CHRS device. In the absence of a plausible parallel claim, Plaintiff's claims are preempted as described in *Riegel* and must be dismissed.

IV. CONCLUSION

For the reasons set forth above, Corin's Motion to Dismiss, ECF 25, and Howmedia's Motion to Dismiss, ECF 28, are GRANTED. Plaintiff's claims are dismissed without prejudice. A

separate Order follows, which will close the case but will afford Plaintiff thirty days to file a motion for leave to amend his claims against Corin and Howmedia, if desired.

Dated: July 23, 2024

/s/
Stephanie A. Gallagher
United States District Judge